

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in this application. The following amendments do not constitute an admission regarding the patentability of the amended subject matter and should not be so construed. Applicant reserves the right to pursue the subject matter of the canceled claims in this or any other appropriate patent application.

Listing of Claims:

1. (Currently Amended) A method of treating or preventing GERD symptoms in a subject in need by administering a pharmaceutical composition within about 60 minutes prior to a meal, wherein the pharmaceutical composition comprising comprises:
 - (a) an amount of at least one acid labile proton pump inhibitor; and
 - (b) at least one buffering agent in an amount sufficient to inhibit or reduce degradation of at least some of the proton pump inhibitor,wherein the composition is administered to the subject ~~a subject prior to a meal and is~~ in an amount effective to maintain gastric pH greater than about 4.0 for at least about 1 hour following the meal.
2. (Currently Amended) The ~~pharmaceutical composition~~ method of claim 1, wherein the composition is in an amount effective to increase the gastric pH of the subject to at least about 3 prior to the meal.
3. (Currently Amended) The ~~pharmaceutical composition~~ method of claim 1, wherein the composition is in an amount effective to increase the gastric pH of the subject to at least about 3 ~~prior~~ within 30 minutes after administration.
4. (Currently Amended) The ~~pharmaceutical composition~~ method of claim 1, wherein a therapeutically effective amount of the proton pump inhibitor is absorbed within about 1 hour after administration.

5. (Currently Amended) The ~~pharmaceutical composition~~ method of claim 1, wherein at least some of the proton pump inhibitor is not enteric-coated.
6. (Currently Amended) The ~~pharmaceutical composition~~ method of claim 1, wherein the composition is in an amount effective to maintain gastric pH greater than about 4.5 for at least about 1 hour following the meal.
7. (Currently Amended) The ~~pharmaceutical composition~~ method of claim 1, wherein the maximum pH is reached within about 30 minutes after administration of the composition.
8. (Currently Amended) The ~~pharmaceutical composition~~ method of claim 1, wherein the maximum pH is reached within about 15 minutes after administration of the composition.
9. (Currently Amended) The ~~pharmaceutical composition~~ method of claim 1, wherein the gastric pH is greater than about 4.0 at least about 50% of a time period up to seven hours.
10. (Currently Amended) The ~~pharmaceutical composition~~ method of claim 1, wherein the gastric pH is greater than about 4.0 at least about 75% of a time period up to seven hours.
11. (Currently Amended) The ~~pharmaceutical composition~~ method of claim 1, wherein the amount of proton pump inhibitor present in the pharmaceutical composition is about 5 to about 500 mg.
12. (Currently Amended) The ~~pharmaceutical composition~~ method of claim 1, wherein the amount of proton pump inhibitor present in the pharmaceutical composition is about 10 mg.
13. (Currently Amended) The ~~pharmaceutical composition~~ method of claim 1, wherein the amount of proton pump inhibitor present in the pharmaceutical composition is about 20 mg.
14. (Currently Amended) The ~~pharmaceutical composition~~ method of claim 1, wherein the amount of ~~the~~ proton pump inhibitor present in the pharmaceutical composition is about 40 mg.

15. (Currently Amended) The ~~pharmaceutical composition~~ method of claim 1, wherein the amount of the proton pump inhibitor present in the pharmaceutical composition is about 80 mg.
16. (Currently Amended) The ~~pharmaceutical composition~~ method of claim 1, wherein the proton pump inhibitor present in the pharmaceutical composition is selected from the group consisting of omeprazole, hydroxyomeprazole, esomeprazole, tenatoprazole, lansoprazole, pantoprazole, rabeprazole, dontoprazole, habeprazole, perprazole, ransoprazole, pariprazole, leminoprazole; or a free base, free acid, salt, hydrate, ester, amide, enantiomer, isomer, tautomer, polymorph, derivative, or prodrug thereof.
17. (Currently Amended) The ~~pharmaceutical composition~~ method of claim 1, wherein the proton pump inhibitor ~~comprises~~ present in the pharmaceutical composition is omeprazole, or a free base, free acid, salt, hydrate, ester, amide, enantiomer, isomer, tautomer, polymorph, derivative, or prodrug thereof.
18. (Currently Amended) The ~~pharmaceutical composition~~ method of claim 1, wherein the proton pump inhibitor present in the pharmaceutical composition is lansoprazole, or a free base, free acid, salt, hydrate, ester, amide, enantiomer, isomer, tautomer, polymorph, derivative, or prodrug thereof.
19. (Currently Amended) The ~~pharmaceutical composition~~ method of claim 1, wherein the proton pump inhibitor ~~comprises~~ present in the pharmaceutical composition is esomeprazole, or a free base, free acid, salt, hydrate, ester, amide, enantiomer, isomer, tautomer, polymorph, derivative, or prodrug thereof.
20. (Currently Amended) The ~~pharmaceutical composition~~ method of claim 1, wherein ~~[[the]]~~ at least about 50% of the total area under a serum concentration time curve (AUC) for the proton pump inhibitor occurs within about 1.75 hours after administration of a single dose of the composition to the subject.

21. (Currently Amended) The ~~pharmaceutical composition~~ method of claim 1, wherein ~~[[the]]~~ at least about 50% of the total area under a serum concentration time curve (AUC) for the proton pump inhibitor occurs within about 1.0 hour after administration of a single dose of the composition to the subject.
22. (Currently Amended) The ~~pharmaceutical composition~~ method of claim 1, wherein the proton pump inhibitor present in the pharmaceutical composition is encapsulated with a material that enhances the shelf-life of the pharmaceutical composition.
23. (Currently Amended) The ~~pharmaceutical composition~~ method of claim 1, wherein the buffering agent present in the pharmaceutical composition is selected from the group consisting of an amino acid, an alkali metal salt of an amino acid, aluminum hydroxide, aluminum hydroxide/magnesium carbonate/calcium carbonate co-precipitate, aluminum magnesium hydroxide, aluminum hydroxide/magnesium hydroxide co-precipitate, aluminum hydroxide/sodium bicarbonate coprecipitate, aluminum glycinate, calcium acetate, calcium bicarbonate, calcium borate, calcium carbonate, calcium citrate, calcium gluconate, calcium glycerophosphate, calcium hydroxide, calcium lactate, calcium phthalate, calcium phosphate, calcium succinate, calcium tartrate, dibasic sodium phosphate, dipotassium hydrogen phosphate, dipotassium phosphate, disodium hydrogen phosphate, disodium succinate, dry aluminum hydroxide gel, L-arginine, magnesium acetate, magnesium aluminate, magnesium borate, magnesium bicarbonate, magnesium carbonate, magnesium citrate, magnesium gluconate, magnesium hydroxide, magnesium lactate, magnesium metasilicate aluminate, magnesium oxide, magnesium phthalate, magnesium phosphate, magnesium silicate, magnesium succinate, magnesium tartrate, potassium acetate, potassium carbonate, potassium bicarbonate, potassium borate, potassium citrate, potassium metaphosphate, potassium phthalate, potassium phosphate, potassium polyphosphate, potassium pyrophosphate, potassium succinate, potassium tartrate, sodium acetate, sodium bicarbonate, sodium borate, sodium carbonate, sodium citrate, sodium gluconate, sodium hydrogen phosphate, sodium hydroxide, sodium lactate, sodium phthalate, sodium phosphate, sodium polyphosphate, sodium pyrophosphate, sodium sesquicarbonate, sodium succinate, sodium

tartrate, sodium tripolyphosphate, synthetic hydrotalcite, tetrapotassium pyrophosphate, tetrasodium pyrophosphate, tripotassium phosphate, trisodium phosphate, trometamol, and mixtures thereof.

24. (Currently Amended) The ~~pharmaceutical composition~~ method of claim 1, wherein the buffering agent in the pharmaceutical composition is selected from sodium bicarbonate, calcium carbonate, magnesium hydroxide, magnesium oxide, potassium bicarbonate, magnesium carbonate and mixtures thereof.
25. (Currently Amended) The ~~composition~~ method of claim 1, wherein the buffering agent in the pharmaceutical composition is present in an amount from about 0.25 mEq/mg to about 2.5 mEq/mg ~~0.1 mEq/mg to about 5 mEq/mg~~ of the proton pump inhibitor.
26. (Currently Amended) The ~~composition~~ method of claim 1, wherein the buffering agent in the pharmaceutical composition is present in an amount from about 0.4 mEq/mg to about 1.5 mEq/mg of the proton pump inhibitor.
27. (Currently Amended) The ~~composition~~ method of claim 1, wherein the pharmaceutical composition comprises ~~comprising~~ from about 200 to about 2000 mg of buffering agent.
28. (Currently Amended) The ~~pharmaceutical composition~~ method of claim 1, wherein the pharmaceutical composition is in the form of a powder, a tablet, a bite-disintegration tablet, a chewable tablet, a caplet, a capsule, an effervescent powder, a rapid-disintegration tablet, or an aqueous suspension or emulsion.
29. (Currently Amended) ~~A pharmaceutical composition~~ The method of claim 1, wherein at least some of the proton pump inhibitor in the pharmaceutical composition is microencapsulated.
30. (Currently Amended) ~~A pharmaceutical composition~~ The method of claim 1, wherein at least some of the proton pump inhibitor in the pharmaceutical composition is micronized.

31. (Currently Amended) ~~A pharmaceutical composition~~ The method of claim 1, wherein at least some of the proton pump inhibitor in the pharmaceutical composition is coated.
32. (Currently Amended) The ~~pharmaceutical composition~~ method of claim 1, wherein the pharmaceutical composition further ~~comprising~~ comprises an excipient.
33. (Currently Amended) The ~~pharmaceutical composition~~ method of claim 32, wherein said excipient is selected from the group consisting of a parietal cell activator, erosion facilitator, flavoring agent, sweetening agent, diffusion facilitator, antioxidant and a carrier material selected from a binder, suspending agent, disintegration agent, filling agent, surfactant, solubilizer, stabilizer, lubricant, wetting agent, diluent, anti-adherent, and antifoaming agent.
34. (Currently Amended) A method of treating or preventing GERD symptoms in at least one subject in need by administering a pharmaceutical composition before a meal, wherein the pharmaceutical composition ~~comprising~~ comprises:
- (a) an amount of at least one acid labile proton pump inhibitor; and
- (b) at least one buffering agent in an amount sufficient to inhibit or reduce degradation of at least some of the proton pump inhibitor,
- wherein the composition is administered ~~to a subject before a meal and in an amount effective to causes a~~ increase [[in]] gastric pH of the subject to at least about 3.0 within about 30 minutes after administration.
35. (Currently Amended) The ~~pharmaceutical composition~~ method of claim 34, wherein a therapeutically effective amount of the proton pump inhibitor is absorbed within about 1 hour after administration of the composition.
- 36-51. (Cancelled)
52. (Original) A method of treating a subject having or at risk of having a gastric acid-related disorder, said subject having difficulty swallowing a pill, capsule or tablet by administering a

pharmaceutical composition according to claim 1, wherein the composition is administered in liquid form.

53. (Original) A method of treating heartburn by administering a pharmaceutical composition according to claim 1.
54. (New) The method of claim 1, wherein upon oral administration of the composition to the subject, a therapeutically effective amount of the proton pump inhibitor is absorbed within about 1 hour after administration.
55. (New) The method of claim 1, wherein upon oral administration of the composition to the subject, a therapeutically effective amount of the proton pump inhibitor is absorbed within about 30 minutes after administration.
56. (New) The method of claim 1, wherein upon oral administration of the composition to the subject, at least about 75% of the proton pump inhibitor is released from the pharmaceutical composition within about 1 hour after administration.
57. (New) The method of claim 1, wherein upon oral administration of the composition to the subject, the subject exhibits a plasma concentration of the proton pump inhibitor of at least about 100 ng/ml at any time within about 15 minutes.
58. (New) The method of claim 1, wherein upon oral administration of the composition to the subject, the subject exhibits a plasma concentration of the proton pump inhibitor of at least about 100 ng/ml at any time within about 30 minutes.
59. (New) The method of claim 1, wherein upon oral administration of the composition to the subject, the subject exhibits a Cmax of greater than about 700 ng/ml after administration.
60. (New) The method of claim 1, wherein upon oral administration of the composition to the subject, the subject exhibits a Tmax within about 1.5 hours after administration.

61. (New) The method of claim 1, wherein upon oral administration of the composition to the subject, the subject exhibits a Tmax within about 1 hour after administration.
62. (New) The method of claim 1, wherein upon oral administration of the composition to the subject, the subject exhibits a plasma concentration of proton pump inhibitor of greater than about 750 ng/ml within about 1 hour after administration.
63. (New) The method of claim 1, wherein upon oral administration of the composition to the subject, the subject exhibits a Cmax of greater than about 500 ng/ml after administration.
64. (New) The method of claim 1, wherein upon oral administration of the composition to the subject, the subject exhibits a Cmax of greater than about 1000 ng/ml after administration.
65. (New) The method of claim 1, wherein upon oral administration of the composition to the subject, the subject exhibits a plasma concentration of proton pump inhibitor of greater than about 425 ng/ml within about 1 hour after administration.
66. (New) The method of claim 1, wherein upon oral administration of the composition to the subject, the subject exhibits a plasma concentration of proton pump inhibitor between about 425 ng/ml and about 1200 ng/ml within about 1 hour after administration.
67. (New) The method of claim 1, wherein upon oral administration of the composition to the subject, the subject exhibits a plasma omeprazole concentration of between about 750 ng/ml and about 2000 ng/ml within about 1 hour after administration.
68. (New) The method of claim 1, wherein upon oral administration of a subsequent dose of the pharmaceutical composition, the subject exhibits a higher plasma concentration of the proton pump inhibitor than the subject exhibited after the initial dose.
69. (New) The method of claim 1, wherein upon oral administration of the composition to the subject, the subject exhibits a Tmax within about 45 minutes after administration.